PREPARATION H SOOTHING RELIEF COOLING- witch hazel aerosol, spray GlaxoSmithKline Consumer Healthcare Holdings (US) LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredients

Witch hazel 20%

Purpose

Astringent

Uses

- helps relieve the local itching and discomfort associated with hemorrhoids
- temporary relief of irritation and burning
- aids in protecting irritated anorectal areas

Warnings

For external use only

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator
- **Warning** avoid spraying in eyes. Contents under pressure. Do not puncture or incinerate. Do not store at temperature above 120°F.
- **Warning** use only as directed. Intentional misuse by deliberately concentrating and inhaling the contents can be harmful or fatal.

Stop use and ask a doctor if

- bleeding occurs
- condition worsens or does not improve within 7 days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- Adults: when practical, cleanse the affected area by patting or blotting with an appropriate cleansing pad. Gently dry by patting or blotting with toilet tissue or a soft cloth before applying the spray.
- apply externally to the affected area up to 6 times daily or after each bowel movement
- children under 12 years of age: consult a doctor
- shake well before using
- hold 3 to 6" away from rectal area, spray to moisten and then wipe off excess, if desired

Other information

■ store at 20-25°C (68-77°F)

Inactive ingredients

aloe barbadensis leaf juice, anhydrous citric acid, benzyl alcohol, dehydroxanthan gum, edetate disodium, glycerin, isobutane, propylene glycol, purified water, sodium benzoate, sodium citrate

Questions?

Call weekdays 9 AM to 5 PM EST at 1-800-99PrepH or 1-800-997-7374

Additional information

No Touch Spray

Do not use if sleeve band around cap is broken or missing

Dist. By: GSK Consumer Healthcare

Warren, NJ 07059

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PAA172637 (Front Carton)

PRINCIPAL DISPLAY PANEL

NDC 0573-2889-01

PREPARATION H

NEW!

soothing RELIEF cooling spray

HEMORRHOIDAL SPRAY

with ALOE

Quickly Soothes and Cools Discomfort Relieves Itching, Burning and Irritation Gentle for Daily Use

NET WT 2.7 OZ (77 g)



PREPARATION H SOOTHING RELIEF COOLING

witch hazel aerosol, spray

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			11411

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0573-2889

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
WITCH HAZEL (UNII: 10114J0U34) (WTCH HAZEL - UNII:10114J0U34)	WITCH HAZEL	200 mg in 1 g

Inactive Ingredients			
Ingredient Name	Strength		
ALOE VERA LEAF (UNII: ZY81Z83H0X)			
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
BENZYL ALCOHOL (UNII: LKG8494WBH)			
DEHYDROXANTHAN GUM (UNII: 63ZP7I1BQO)			
EDETATE DISODIUM (UNII: 7FLD91C86K)			
GLYCERIN (UNII: PDC6A3C0OX)			
ISOBUTANE (UNII: BXR49TP611)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
WATER (UNII: 059QF0KO0R)			
SODIUM BENZOATE (UNII: OJ245FE5EU)			
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:0573-2889- 01	77 g in 1 CANISTER; Type 0: Not a Combination Product	04/12/2021		

		Marketing Information				
ation Number or Monograph Citation	Marketing Start Date	Marketing End Date				
	04/12/2021					
		Citation Date				

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

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